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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/603,094

06/25/2003

Don J. Diamond

1954-410

7356

6449

7590

05/30/2008

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WASHINGTON, DC 20005

EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/603,094	<b>Applicant(s)</b> DIAMOND, DON J.	
	<b>Examiner</b> LOUISE HUMPHREY	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Office Action is in response to the amendment filed 27 February 2008.

Claims 1-14 are pending. Claims 3, 4 and 12-14 are withdrawn.

Claims 1, 2 and 5-11 are currently examined.

### ***Affidavit or Declaration under 37 CFR 1.132***

The Diamond Declaration under 37 CFR 1.132 filed on 27 February 2008 is insufficient to overcome the rejection of claims 1, 2 and 5-11 based upon the Zaia reference (2000, IDS 08 March 2004, hereinafter "Zaia") in view of WO 01/22972 (05 April 2001) by Krieg *et al.* (hereinafter "Krieg") as set forth in the last Office action because the affidavit includes statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716. The Diamond Declaration merely sets forth the fact that Zaia does not teach unlipidated fusion peptides and states the inventor, Diamond's opinion that the teachings of Zaia combined with Krieg do not teach or render obvious an unlipidated peptide without any reasoning or evidence.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 2, 5, 6 and 9-11 under 35 U.S.C. §102(b) as being anticipated by Zaia *et al.* (2000, No. QQQQ in IDS filed on 08 March 2004) is **withdrawn** in response to Applicant's amendment, which adds a new limitation "unlipidated" in the claims.

Applicant's arguments with respect to claims 1, 2, 5, 6 and 9-11 have been considered but are moot in view of the **new ground of rejection** as necessitated by Applicants' amendment.

Claims 1, 2, 5, 6 and 9-11 are rejected under 35 U.S.C. §102(a) as being anticipated by BenMohamed *et al.* (May 2002, No. Q in IDS filed 08 March 2004, hereinafter "BenMohamed").

The instant claims are directed to an unlipidated cytomegalovirus (CMV) vaccine comprising a fusion protein comprising a T helper epitope, PADRE, fused to a CMV CTL epitope pp65<sub>495-503</sub>.

BenMohamed teaches an unlipidated peptide containing CMV covalently linked to PADRE. See the paragraph bridging the left and right column on page 114. The peptide vaccine comprises sterile PBS and 10% DMSO as a carrier. See page 114,

right column, last paragraph, Animals and immunization procedures. Thus, the instant claims are anticipated by BenMohamed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1, 2 and 5-11 under 35 U.S.C. §103(a) as being obvious over Zaia *et al.* (2000, IDS 08 March 2004, hereinafter "Zaia") in view of WO 01/22972 (05 April 2001) by Krieg *et al.* (WO 01/022972 filed 05 April 2001, hereinafter "Krieg") **is withdrawn** in response to Applicants' amendment.

Applicant's arguments with respect to claims 1, 2 and 5 -11 have been considered but are moot in view of the **new ground of rejection** as necessitated by Applicants' amendment.

Claims 1, 2 and 5-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over BenMohamed *et al.* (May 2002, No. Q in IDS filed 08 March 2004, hereinafter "BenMohamed") in view of Krieg *et al.* (WO 01/022972 filed 05 April 2001, hereinafter "Krieg").

The instant claims directed to an unlipidated cytomegalovirus (CMV) vaccine comprising a fusion protein comprising a T helper epitope, PADRE, fused to a CMV CTL epitope pp65<sub>495-503</sub>, and further comprising a DNA adjuvant.

BenMohamed discloses both a lipopeptide comprising CMV pp65<sub>495-503</sub> and PADRE and an unlipidated version of the fusion peptide. See the paragraph bridging the left and right column on page 114.

BenMohamed does not describe adding a DNA adjuvant to the unlipidated fusion peptide comprising PADRE and CMV pp65<sub>495-503</sub>. However, BenMohamed suggests that the use of adjuvants is often essential for the induction of effective immune responses, and for mucosal immunization they are particularly important as subunit vaccines may lead to a state of immunologic unresponsiveness, known as peripheral tolerance, when given via this route. BenMohamed further discloses that the purpose of lipidation of the fusion peptide is to bypass the use of the most powerful yet toxic adjuvants, which are unacceptable for human use because of their severe diarrhoeagenic property. See page 114, left column, first paragraph.

Krieg describes immunostimulatory nucleic acids. Specifically, Krieg discloses a DNA that matches the sequence of the instantly claimed SEQ ID NO:10. See page 57, SEQID NO:959, in Table A.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the BenMohamed's unlipidated CMV pp65<sub>495-503</sub>-PADRE fusion peptide vaccine by adding a DNA adjuvant as taught by Krieg. It would also be obvious to one skilled in the art to add a DNA adjuvant in lieu of lipidation as routine optimization of a vaccine. The skilled artisan would have been motivated to do so to enhance the amount of immune response elicited by the CMV pp65 CTL epitope. There would have been a reasonable expectation of success, given that these DNA adjuvants

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preferentially activate non-rodent immune cells such as B cells, natural killer cells and monocytes, as taught by Krieg, and that the DNA adjuvant and the lipid chains are functionally equivalent. Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made

### ***Conclusion***

No claim is allowable.

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./  
Examiner, Art Unit 1648

/Bruce Campell/  
Supervisory Patent Examiner, Art Unit 1648